UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA,	еx	rel.
JULIE LONG,		

Plaintiffs,

Civil Action No. 16-CV-12182-FDS

v.

JANSSEN BIOTECH, INC.,

Defendant.

DEFENDANT'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO COMPEL
RELATOR TO AMEND INTERROGATORY RESPONSES SO THEY ARE
CONSISTENT WITH STATEMENTS MADE TO THE COURT IN
OPPOSITION TO DEFENDANT'S MOTION FOR
JUDGMENT ON THE PLEADINGS

Plaintiff-Relator Julie Long made factual representations to Judge Saylor in her briefing and at oral argument opposing Defendant Janssen Biotech, Inc.'s ("Janssen's") case-dispositive Motion for Judgment on the Pleadings (ECF No. 377) that are inconsistent with her prior sworn interrogatory responses. Specifically, Relator asserted before Judge Saylor that a publicly-disclosed, twenty-three page presentation cited by Janssen was irrelevant because she does not allege that providing materials of this type to doctors constituted an unlawful kickback. That representation to Judge Saylor directly contradicts Relator's interrogatory responses, which have consistently and unambiguously stated that Janssen violated the Anti-Kickback Statute ("AKS") each and every time it provided one of 36 enumerated presentations, and that every single claim a doctor submitted after receiving one of these presentations was "false" under the False Claims Act ("FCA"). Because the identified presentations have the same kind of substantive content as the document that Relator now agrees was not a kickback, these contradictory statements cannot be squared.

Relator could easily resolve the conflict created by her recent representations, which necessarily render her interrogatory responses inaccurate, by amending her interrogatory responses to align with her representations to Judge Saylor. Relator has refused to do so.

Janssen cannot defend itself, and this case cannot proceed in an orderly fashion, unless Relator clearly states her position in a binding interrogatory response. Janssen is entitled to know whether Relator contends that providing a presentation of this type constituted a kickback in violation of the AKS (as her interrogatories state), or whether she instead alleges something else (as she told Judge Saylor). And the burden on Relator is minimal. Therefore, pursuant to Federal Rule of Civil Procedure 37(a) and Local Rule 37.1, Janssen submits this memorandum of law in support of its motion to compel Relator to amend her interrogatory responses to conform

to the representations she made to Judge Saylor and to clearly explain her theory of liability in this case.

BACKGROUND

Relator's claims in this case pertain to a set of presentations that Janssen representatives made to physician practices, which included information about opening and operating an inoffice infusion ("IOI") suite for the purpose of administering Janssen's products Remicade and Simponi ARIA. Interrogatory 2 asked Relator to identify all services that she alleges violated the AKS. In her response, Relator identified 36 specific presentations by name, and she claimed that provision of each of these 36 presentations constituted unlawful remuneration. For example, Relator identified a presentation that Janssen produced titled "Infusion Suite Scheduling and Staffing." Ex. 1 (Pl.'s 4th Supp. Objs. & Resp. to Def.'s Interrog. No. 2) at 10; Ex. 2 (JANSSENBIO-049-00015292). Between October 2021 and June 2023, Relator amended her response to Interrogatory 2 four times, each time revising her list of presentations.

Throughout this case, Relator's other interrogatory responses—by reference to her response to Interrogatory 2—have consistently asserted that an unlawful kickback took place each and every time a Janssen representative provided one of the identified presentations to a physician, and that every claim thereafter submitted by a physician was "false" under the FCA. This is demonstrated by Relator's response to Interrogatory 12:

Plaintiff alleges that *all claims for payment* for Remicade, Simponi ARIA, and related infusion procedures . . . on or after October 28, 2010 and *after the Phase I Account received one or more of the services, presentations, or programs identified in Plaintiff's response to Interrogatory 2* constitute claims that were false or fraudulent in violation of 31 U.S.C. § 3729(a)(1)(A) & (B).

Ex. 3 (Pl.'s Supp. Objs. & Resp. to Def.'s Interrogs. 6 to 18) at 19 (emphasis added).¹

This is a kickback case. Despite the allegation in her sworn interrogatory responses that every delivery of one of the 36 written presentations was itself a kickback, Relator's recent briefing to the Court on Janssen's Motion for Judgment on the Pleadings stated, for the first time, that she does not contend that providing a presentation of this type was a kickback. The conflict between Relator's interrogatory responses and her statements in opposing Janssen's dispositive motion is clearly illustrated by her treatment of a 23-page Office-Based Infusion Guide (the "Guide") that was addressed in Janssen's Motion for Judgment on the Pleadings, and which Relator told Judge Saylor was not a kickback.

As is set out in detail in Janssen's Motion for Judgment on the Pleadings and Janssen's Reply, this Guide specifically addressed a variety of topics that are identical to the subjects of the presentations at issue here, including the financial implications of opening an IOI suite, tips for "[r]esource [o]ptimization," and "[p]atient [c]omfort' recommendations." See ECF No. 388 at

¹ See also id. at 12, Resp. to Interrog. 10 ("Plaintiff alleges that Defendant's offering and provision . . . of each form of remuneration identified in Plaintiff's response to Interrogatory 2 to the Phase 1 Accounts violated the Anti-Kickback Statute." (emphasis added)); id. at 14, Resp. to Interrog. 11 ("The services and related presentations and programs identified in the responses to Interrogatories 2 and 10 constitute 'remuneration' as that term is used in the Anti-Kickback Statute." (emphasis added)); id. at 21, Resp. to Interrog. 13 ("In submitting claims for payment for Remicade, Simponi ARIA, and related infusion services after receiving the services and related presentations and programs identified in the response to Interrogatory 2, the providers falsely represented that they were complying with the certification made in their enrollment agreements." (emphasis added)); id. at 23-25, Resp. to Interrogs. 14 & 15 ("As a result of its knowing and willful offering and provision of the services and related presentations and programs identified in Plaintiff's response to Interrogatory 2 to induce health care providers . . . to prescribe and infuse Remicade and Simponi ARIA to Medicare beneficiaries in violation of the Anti-Kickback Statute, Defendant caused the health care providers . . . to present claims for reimbursement to Medicare that were false or fraudulent under 31 U.S.C. § 3729(a)(1)(A)." (emphasis added)).

4–5; *see also* Ex. 4 (Office-Based Infusion Guide). Moreover, the Guide referenced additional topics and tools that Janssen made available to practices while also encouraging the practices to have further discussions with Janssen representatives. *See, e.g.*, Ex. 4 at 7 ("Please ask your local Centocor representative to demonstrate the REMICADE Practice Management Assistant, which provides a detailed assessment and shows how payer mix may impact your financial results."); *id.* at 5, 7, 13–14 (discussing tools incorporated into "the REMICADE Practice Management Kit"); *id.* at 8 (providing a customizable "Financial Impact Worksheet" to help practices "determin[e] whether or not to perform REMICADE infusions in the office setting" by helping practices "estimate projected monthly revenues from" infusing Remicade); *id.* at 18 (noting that a sample practice "received an in-service training from a Centocor Reimbursement Specialist to establish customized billing procedures that facilitate reimbursement and maximize efficiency.").

In her Response to Janssen's Motion for Judgment on the Pleadings, Relator argued that the Guide cited by Janssen was legally irrelevant to application of the FCA's public disclosure bar because Relator does not argue that the provision of such materials, standing alone, constituted a kickback. For example, in her Sur-Reply, Relator told Judge Saylor that the presentation cited by Janssen was irrelevant because she "does [not] allege that merely making available or providing a written guide regarding setting up an infusion suite constitutes illegal remuneration." ECF No. 389 at 7. Instead, she claimed that her "case concerns Janssen's provision of free services, not free pamphlets." ECF No. 381 at 17. And in oral argument on Janssen's Motion for Judgment on the Pleadings, Relator's counsel described her claims as pertaining to a "collection of business services and support that was provided to select accounts after they had opened the IOI," seemingly indicating that Relator does not intend to claim that

each individual presentation constituted a separate instance of unlawful remuneration rendering all claims thereafter "false," as she explicitly stated in response to Interrogatory 12. See Hr'g Tr. (May 18, 2023) at 37:9–10.

In light of the inconsistency with Relator's past discovery responses, Janssen sent letters to Relator on May 25, 2023 and June 22, 2023 asking Relator to answer a simple question: "whether you contend that Janssen's act of simply providing a presentation identified in your response to Interrogatory 2, either orally or by giving a practice a copy of the presentation, was a violation of the Anti-Kickback Statute." Ex. 6 (June 22, 2023 Letter from M. Dunn); see also Ex. 5 (May 25, 2023 Letter from M. Dunn).

In response to these letters, Relator revised the list of presentations in her response to Interrogatory 2 that she claims were kickbacks, but she did nothing to address Janssen's question. Instead, Relator's counsel argued in emails that they would not "share [their] views regarding hypothetical conduct or made up scenarios." Ex. 7 (Emails Between C. Preston and M. Dunn) at 5. There has been no telephonic meet and confer between the parties on this issue, because although Janssen requested a meet and confer four times, in emails dated June 30, July 7, July 10, and July 11, 2023, counsel for Relator repeatedly refused Janssen's requests for a meet and confer by claiming there was no issue in dispute between the parties. See id. at 1-3.2

ARGUMENT

Relator's recent statements to the Court in opposing Janssen's Motion for Judgment on the Pleadings are inconsistent with her sworn interrogatory responses. In communications

² Relator's refusal to meet and confer in good faith in violation of Local Rule 37.1 is an independent basis to grant this motion.

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concerning this issue, Relator has insisted that her representations to Judge Saylor were accurate. Therefore, she should be required to amend her interrogatory responses so they no longer state—contrary to what she told Judge Saylor—that each and every time Janssen provided any one of the enumerated 36 presentations, Janssen violated the AKS, and that all subsequent claims submitted by the practices that received one of those presentations violated the FCA. The burden imposed by requiring Relator to amend her interrogatory responses is minimal, and it is far outweighed by the need for clarity about Relator's theory of liability as the case moves forward. Such requests concerning the basis for Relator's claims are uncontroversial, and the subject at issue here is fundamental to Relator's claims in this case. *See* Fed. R. Civ. P. 33(a)(2). Furthermore, to the extent that Relator's existing interrogatory responses are incorrect or misleading, Relator has a duty to supplement those responses. Fed. R. Civ. P. 26(e).

In response to Janssen's request for clarity, Relator has asserted via email that, "In this case, the meaning of 'presentations' obviously is not limited to slide decks that Janssen utilized; rather 'presentations' refers to the entire consultative meetings or programs through which Janssen provided the alleged illegal services." See Ex. 7 at 7 (emphasis added). But that is not what the interrogatory responses say.

Moreover, counsel's email assurances are not binding on Relator and, if anything, only add confusion. Relator's interrogatory responses indicate that a single provision of any of the 36 presentations—standing alone and without more—violates the AKS (Resp. to Interrogatory 10), constitutes illegal remuneration (Resp. to Interrogatory 11), renders all subsequent claims for reimbursement "false" under the FCA (Resp. to Interrogatory 12), and evinces a "knowing and willful" intent to violate the AKS (Resp. to Interrogatories 14 & 15). *See* Ex. 3. These responses in no way indicate that liability attaches only as a result of "entire consultative meetings or

programs," whatever that may mean. Again, this is a kickback case. Janssen should not be forced to guess what Relator alleges constituted an illegal kickback. And Relator should not be permitted to preserve her ability to modify her position on this fundamental issue at a later stage of this litigation.

Relator has refused to amend her interrogatories or clearly explain her theory of liability in a way that comports with her representations to Judge Saylor on the basis that Janssen's request for clarification is premised on a "hypothetical." *See* Ex. 7 at 5 ("[W]e're not going to answer questions or share our views regarding hypothetical conduct or made up scenarios."). However, there is nothing hypothetical about this issue. These are Relator's claims. What she alleges constitutes illegal remuneration and kickbacks triggering FCA liability is core to the case and directly within her knowledge. Indeed, she personally delivered the services that she alleges were kickbacks and is uniquely situated to state what, exactly, the allegedly unlawful remuneration was. In other words, as the person who both delivered the purported remuneration and the plaintiff who now alleges that the remuneration constituted an illegal kickback, she is the only person who can answer what specific conduct allegedly crossed the line from legality (*e.g.*, providing one of the 36 presentations) to illegality. There is simply no justification for her refusal to provide clarity on this fundamental aspect of her claims in this case.

Janssen is entitled to know with specificity which activities she claims violated the law, and which did not. And if Relator's briefing to the Court misrepresented her claims in this case, she should correct that misrepresentation. As it stands now, Janssen does not know what conduct Relator alleges constituted a kickback in violation of the AKS. Relator's studied ambiguity on this issue is contrary to the Federal and Local Rules, and it impedes Janssen's ability to prepare its defense. *See* ECF No. 322 at 9–10 (granting Relator's motion to compel

interrogatory responses on the basis that "both sides will be required to challenge each other's claims and defenses at summary judgment, and to do so they will need to fully understand each other's positions"); see also Brown v. Wal-Mart Assocs., Inc., 616 F. Supp. 3d 137, 145 (D. Mass. 2022) ("[T]he purpose of pretrial discovery is to 'make trial less a game of blindman's bluff and more a fair contest with the basic issues and facts disclosed to the fullest practicable extent." (quoting Wamala v. City of Nashua, No. 09-CV-304, 2010 WL 3746008, at *1 (D.N.H. Sept. 20, 2010))); Eveden, Inc. v. N. Assurance Co. of Am., No. 10-10061, 2012 WL 12345021, at *1 (D. Mass. Feb. 7, 2012) (compelling response to contention interrogatories, noting that "defendant is entitled to the information that forms the basis for the plaintiff's claims.").

CONCLUSION

For the reasons stated above, Janssen respectfully requests that this Court order Relator to supplement her interrogatory responses to align with what she told Judge Saylor and to specifically identify the conduct by Janssen that forms the basis for her claims.

Dated: August 9, 2023

/s/ Jason C. Raofield

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CERTIFICATE OF SERVICE

I hereby certify on this 9th day of August, 2023, that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Jason C. Raofield

Jason C. Raofield (BBO No. 641744)